Pricing & Reimbursement

2020

Third Edition

Contributing Editor:
Grant Castle

glg global legal group

CONTENTS

United Kingdom

Grant Castle, Brian Kelly & Raj Gathani
Covington & Burling LLP

Abstract

The UK has a large and complex healthcare system, under which the National Health Service ("NHS") funds the vast majority of medicines prescribed to patients.

The complexities of the system mean there is no single pathway to NHS reimbursement for a medicinal product, nor a universal reimbursement list. If and how the NHS funds a product often depends on the setting in which the NHS uses it. However, guidance from the National Institute for Health and Care Excellence ("NICE") plays an important role in determining whether the NHS will support the use of a product. The UK has price control policies for branded medicines but, in general, leaves the price of generic products open to market forces.

NHS drug expenditure continues to increase, albeit growth rates vary significantly depending on product type. Reasons for this include a growing and ageing population, with specific needs, as well as the launch of costlier high-tech and rare disease medicines into the UK. Although the Government has increased funding for the NHS, particularly in response to COVID-19, there continues to be significant downward pressure on drug budgets. In light of this, there is a clear trend for the NHS and other state organisations to involve themselves directly and indirectly in drug pricing and policy. As such, the landscape for pricing and reimbursement is increasingly multi-layered. Commercial negotiations with the NHS and procurement initiatives often have a significant effect on the actual selling price of a product.

Market overview

The UK comprises four constituent nations: England; Wales; Scotland; and Northern Ireland. The UK has a population of approximately 66.4 million people, with the vast majority (approximately 55.9 million) resident in England. There is a well-developed healthcare market in the UK, dominated by a large and sophisticated public healthcare system, the NHS. The NHS is almost entirely state-funded and mostly free to patients at the point of need.

When considering pricing and reimbursement in the NHS, it is important to keep two points in mind. Firstly, the structure and organisation of the NHS varies across the four nations of the UK, though many key concepts are similar. For the sake of simplicity, this chapter focuses primarily on the NHS in England, which is by far the largest market. Secondly, the way the NHS pays for medicines differs considerably between those supplied in "primary care" (i.e., prescribed by General Practitioners or other community prescribers and dispensed in a community pharmacy or by a dispensing doctor) and "secondary care" (i.e., in hospitals, clinics and similar settings). This distinction is relevant throughout this chapter.

In England, the NHS spent an estimated £18.9 billion on medicines in 2018/19, without taking discounts into account. That represents a 4.1% increase on the prior year and is broadly

consistent with an average 5% annual growth rate since 2010/11. That growth is almost entirely attributable to medicines dispensed in hospital settings (i.e., secondary care), the cost of which has more than doubled since 2010/11. In 2018/19, spending on hospital medicines accounted for 53.7% of NHS's total expenditure on medicines, which is an increase of 11.1% on the previous year.

By contrast, spending on medicines in primary care fell by 2.8% in 2018/19. The gross amount spent has broadly remained the same since 2010/11, despite the fact that the volume of medicines dispensed in primary care has risen by an average of 3% each year. This demonstrates the downward pressure on prices for medicines that are mainly dispensed by community pharmacies to non-hospitalised patients.

Historically, the NHS in England spends approximately three-quarters of its drugs budget on branded products.

Pharmaceutical pricing and reimbursement

Regulatory classification

Classification of medicinal products

The Human Medicines Regulations 2012 created three broad regulatory classes of medicines:[1]

1. "Prescription-only Medicines" ("POMs");
2. "General Sale Medicines", which consumers may purchase without a prescription; and
3. "Pharmacy Medicines", which consumers may purchase without a prescription but only from a pharmacy.[2]

The regulatory classification of a new medicine will depend on a number of factors, including whether: (i) the marketing authorisation designates it as a POM, a General Sale Medicine or a Pharmacy Medicine; (ii) by statute the product must fall into a particular category; or (iii) the Medicines and Healthcare products Regulatory Agency ("MHRA") or the European Commission has allocated the product to a particular category.

In principle, NHS reimbursement is available to all three classes of medicines. However, the NHS increasingly focuses its expenditure on POMs and to that end, the NHS aims to dissuade clinicians from prescribing medicines available over the counter.[3]

Eligibility for reimbursement

In primary care, any medicinal product commercially available in the UK is, in principle, eligible for reimbursement (i.e., the NHS agrees to refund the cost of the medicine to the dispensing pharmacist/doctor). The main exceptions to this are where the NHS has "black-listed"[4] a product in the Drug Tariff (the monthly list of reimbursement prices in primary care) or has placed conditions on reimbursement (e.g., through the so-called "Selected List" in the Drug Tariff).[5]

In secondary care, eligibility for reimbursement is more localised and there is greater scope for variation. Prescription, treatment and supply often take place within a single NHS organisation (e.g., a hospital), which gives that organisation a degree of autonomy over the medicines it chooses to fund (although this autonomy is shrinking as the NHS takes a more centralised approach to achieving cost-efficiency). CCGs (as defined in section "Who is/are the payer(s)?" below), NHS Hospital Trusts and other stakeholders often have their own policies and formularies setting out which products are and are not available to a clinician to prescribe. Prescribers in secondary care settings usually only deviate from these policies for clinically justified reasons, such as an individual patient's exceptional circumstances or requirements.

In both primary and secondary care settings, guidelines issued by NICE play an important

role in determining whether the NHS funds a product and, in practice, whether clinicians would prescribe the product to NHS patients (see section, "How is the reimbursement amount set?" below, which discusses NICE guidelines).

Who is/are the payer(s)?

The NHS ultimately funds the vast majority of POMs supplied to patients in the UK. In England only, it recovers a small fraction of its costs through flat-rate prescription charges, payable by a small minority of patients (usually, adults aged under 60 in full-time employment and earning over a certain threshold). The UK has a smaller – but ever-growing – private healthcare market, funded by patients themselves or through private insurance.

Which NHS organisation is responsible for funding ("commissioning") a medicine and how it arranges that funding are complex questions, which often hinge on the type of treatment provided and the treatment setting (primary or secondary care). The main payers and payment structures in England are as follows:

- The NHS has responsibility for commissioning primary care in England, though these days there are many Clinical Commissioning Groups ("CCGs") (discussed further below) co-commission primary care services with the NHS. The reimbursement mechanism in primary care is largely centralised under the Community Pharmacy Contractual Framework. Essentially, contractors who dispense products in primary care will receive a fixed reimbursement price for a particular product.
- Commissioning in secondary care is effectively the responsibility of approximately 200 local CCGs.[6] CCGs receive funding from the NHS and it is for them to obtain value for money in terms of the products and services they make available.
- The NHS commissions Specialised Services (which include treatments for certain cancers, genetic disorders or complex medical or surgical conditions) and Highly Specialised Services for rare diseases (typically to treat around 500 patients per year). These mechanisms allow the NHS to provide centralised funding for high-cost products that individual CCGs may be reluctant to fund.
- The NHS is responsible overall for commissioning certain "public health" services (such as vaccination programmes), though it works closely with other actors such as Public Health England to fulfil these duties.

What is the process for securing reimbursement for a new pharmaceutical product?

As noted above, the NHS funds treatments in a number of different ways. This means there is no single pathway to securing NHS reimbursement for a new product.

Nonetheless, NICE is often considered the gatekeeper to reimbursement, because a positive recommendation for a product or treatment from NICE obliges the NHS to make funding available for it, usually within three months of the recommendation.[7] A negative recommendation from NICE does not necessarily mean a product is ineligible for reimbursement. However, unless other funding arrangements are in place, it provides commissioners with a basis to resist or delay funding. As a matter of practice, NHS clinicians usually prescribe products according to NICE guidelines.

In response to COVID-19, NICE has published a number of rapid-review guidelines, which can focus on the use of products during the epidemic. These are not subject to NICE's standard procedures and methodologies and are continuing to evolve. As such, this chapter does not provide a detailed commentary on these rapid-review guidelines.

NICE topic selection

NICE's aim is to conduct a health technology appraisal for all new significant drugs and

indications launched in the UK. NICE would typically scan for significant new products and indications 15 to 20 months before regulatory approval. Manufacturers of new products may make suggestions for an appraisal though UK PharmaScan (an industry horizon-scanning directory).

From April 2019, NICE charges companies up to £126,000 for conducting technology appraisals.

NICE assessment

NICE evaluates whether the NHS should fund products or treatments (which NICE refers to as "technologies") based on clinical and cost-effectiveness assessments. In summer 2019, NICE began the process of reviewing its methodologies, including how it conducts health technology appraisals. NICE intends to implement a new system by summer 2021, with the aim of applying common principles to reviewing drugs, medical devices and diagnostics. Currently, NICE has a standard assessment methodology as well as variants for specific types of products (such as certain cancer or highly specialised drugs, see "NICE's Methodology for Certain Products – Cancer Drugs and Highly Specialised Technologies", below). The common thread is NICE's focus on a technology's incremental cost-effectiveness ratio ("ICER") against an existing reference based on the quality-adjusted life year ("QALY"). These are established health economic concepts that seek to quantify the relative utilities of a technology.

NICE's Standard Assessment Methodology

For most conventional products, NICE will issue a positive recommendation if it assesses a product to have an ICER, usually against an existing reference, of less than £20,000. NICE may apply its discretion to recommend technologies with ICERs between £20,000 and £30,000, where justified on certain grounds, such as the innovative nature of a drug. Under its standard methodology, it is rare for NICE to give a positive recommendation to a technology whose ICER exceeds £30,000. However, NICE has additional discretion where products are considered "life extending" in end-of-life scenarios (e.g., many oncology products fall into this category). In those situations, NICE may recommend a product with an ICER of up to £50,000.

NICE's cost-per-QALY thresholds have remained fixed for a number of years. Inflationary pressures, and an increased industry focus on rare diseases and other high-cost treatments, mean that it is increasingly difficult to bring certain new products below the thresholds in order to receive a positive recommendation.

NICE's Budget Impact Test

Introduced in April 2017, the "Budget Impact Test" is an additional step for NICE assessments. Any product that NICE has assessed to be cost-effective but is likely to cost the NHS more than £20 million in any of the first three years of its use must be subject to further negotiations between the supplier and the NHS to bring the overall cost down. If these negotiations are unsuccessful, the NHS may apply to NICE to delay funding the product by up to three years, or longer in exceptional cases. The Budget Impact Test was a controversial measure, as many felt it undermined NICE's independent role and brought it closer to helping to manage the NHS' budget. In the second half of 2017, the Association of the British Pharmaceutical Industry ("ABPI") launched unsuccessful court proceedings to challenge the legality of the test.

Patient Access Schemes

When a product does not meet NICE's cost-effectiveness criteria, NICE may still give it a

positive recommendation if the drug's supplier alters its commercial proposition through an agreed Patient Access Scheme. These are formal pricing agreements, provided for under the Voluntary Scheme (see section, "How are drug prices set? What is the relationship between pricing and reimbursement?", below) between a supplier and the NHS that make a product more affordable (e.g., by way of a price discount, rebates, free-stock or outcome-based pricing). The commercial details are usually kept confidential. NICE's Patient Access Scheme Liaison Unit advises the NHS on the feasibility of any proposed scheme.

Managed Access Agreements

Where the clinical data supporting a NICE application are uncertain, NICE may recommend a product subject to a Managed Access Agreement. These agreements enable NHS patients to access treatment, while allowing the company to collect real world data for a NICE re-appraisal. The commercial terms of these agreements are usually confidential, though they often contain an overall budget-impact cap.

NICE's methodology for certain products – Cancer drugs and Highly Specialised Technologies

When evaluating specialist and high-cost technologies, NICE may depart from its standard methodology. For example:

- There is a specific assessment pathway for "Highly Specialised Technologies" ("HST"), which treat rare and specialist conditions. The HST process is only available to products that satisfy certain requirements, including:
  - The target patient group is distinct for clinical reasons and sufficiently small that treatment will usually be concentrated in very few centres in the NHS.
  - The condition is chronic and severely disabling.
  - The technology has the potential for lifelong use.

  For these products, the conventional NICE appraisal builds in certain allowances to accommodate likely higher cost, and often more limited, clinical data. NICE will usually recommend HSTs that have an ICER of less than £100,000. It has discretion in certain circumstances to recommend products above that threshold, usually up to ICERs of £300,000. NICE has assessed a small number of products using the HST process and to date, has issued 12 pieces of final guidance in more than six years.
- The Cancer Drugs Fund ("CDF"), is in place to enable faster access to promising new cancer treatments. Following its relaunch in 2016, the CDF aims for all new systemic cancer drugs to receive a fast-tracked NICE appraisal. So far, 79 new oncology drugs treating 160 different indications have benefitted from CDF review. NICE will recommend a product to receive funding from the CDF, at a negotiated price, if it has the potential to satisfy the criteria for routine commissioning, but there is clinical uncertainty that needs further investigation (i.e., through data collection in the NHS or clinical studies). The drug will remain available within the CDF while more evidence becomes available, at which point NICE will subject it to one of its standard technology-appraisal processes. The CDF has provided a route to NHS funding for a number of highly-innovative, high-cost oncology technologies, including CAR-T and certain immuno-oncology therapies.

NICE appeals

Generally, the manufacturer of the product under review, patient groups or clinician organisations who have participated in the assessment may appeal the outcome of a NICE assessment to the NICE Appeal Panel. There are three possible grounds for appeal, which mirror the grounds for judicial review in the English Courts:

1. that NICE has failed to act fairly;
2. the recommendation is unreasonable in light of the evidence submitted; and/or
3. NICE has acted unlawfully or has exceeded its legal powers.

Most appeals are under the first two grounds but, in recent years, some successful appeals against NICE determinations have invoked novel human rights' considerations of the affected patient groups (e.g., children), which are essentially claims that NICE has acted unlawfully.

If an appeal to NICE's Appeal Panel is unsuccessful, a party may challenge the decision by way of judicial review in the High Court.

How is the reimbursement amount set?

In primary care, the NHS usually reimburses products: (i) for the amount set out in the Drug Tariff (if the product is listed there); (ii) at the "NHS list price"; or (iii) in other cases for the net price at which the dispensing pharmacy/doctor purchased the product. The Drug Tariff lists the reimbursement amount for commonly used, mostly generic products. The NHS reviews Drug Tariff prices each month, based on a survey of the market. The NHS list price applies mainly to branded products and is set in accordance with the Voluntary or Statutory Schemes (see section, "How are drug prices set? What is the relationship between pricing and reimbursement?" below).

The concept of a "reimbursement amount" is less relevant in secondary care because the NHS usually operates a *payment by results* model. Under this model, providers receive an amount per patient treated, based on the treatment provided, the length of a patient's stay, the complexity of their needs, etc. In most cases, this does not take the price of individual products directly into account. However, that is not always the case and the NHS will take a price-focused approach to secondary care products.

How are drug prices set? What is the relationship between pricing and reimbursement?

The Secretary of State for Health has statutory power to limit the price of medicines supplied to the NHS (section 262, NHS Act 2006). However, significant price control mechanisms only really exist for branded products and not generics (whose prices are broadly controlled by market forces). Branded medicines supplied to the NHS are subject to one of two price control schemes: the Voluntary Scheme for Branded Medicines Pricing and Access ("Voluntary Scheme"); or the so-called "Statutory Scheme".

Voluntary Scheme

As the name suggests, the Voluntary Scheme is an opt-in arrangement, agreed between the innovative pharmaceutical industry body, the Association of the British Pharmaceutical Industry ("ABPI") and the Department of Health. In one form or other, the Voluntary Scheme has been running in the UK since 1957. The current scheme came into effect on 1 January 2019 and will run for five years.

The Voluntary Scheme contains complex arrangements for price and profit control. Below are some key features:

- The Voluntary Scheme aims to cap increases in the amount the NHS spends on branded medicines, which companies that have opted into the Scheme ("Members") supply, to 2% growth *per annum*. To stay within this cap, Members must pay the Department of Health a fixed percentage of their net sales of branded medicines supplied to the NHS ("Scheme Payments"), with certain exceptions. Scheme Payments are designed to offset anticipated growth above the agreed 2% limit. Scheme Payment percentages are fixed for one calendar year and apply scheme-wide. The percentage payable depends on the difference between the agreed growth rate and projected growth in sales. Scheme Payments are set at 5.9% of net sales for 2020 (the figure was 9.6% in 2019 and the original prediction for 2020 was 14.2%).
- Members who are small companies (i.e., essentially, those whose sales of branded products to the NHS total less than £5 million in the previous year) are exempt from

making Scheme Payments. For medium-sized companies (i.e., essentially, those whose sales of branded products to the NHS total between £5 million and £25 million in the previous year), the first £5 million of sales may be exempt from Scheme Payments.

- Importantly, not all branded medicines supplied by Members are subject to Scheme Payments. Medicines containing new active substances sold to the NHS within 36 months of their marketing authorisation are outside the net of Scheme Payments. However, sales of those products will still contribute to calculating expenditure grown across the scheme.
- The Voluntary Scheme also contains pricing controls. A Member may not increase the list price of a product without the prior approval of the Department of Health, which (amongst other things) requires a justification for the increase and an assessment of the Member's profits. In order to avoid stifling innovation, Members have the freedom to set the list price of medicines containing new active substances launched in the UK within 36 months of the grant of a marketing authorisation. However, this still requires a Member to confirm that its intended selling arrangements to the NHS will take cost-effectiveness into account. In other words, very high prices would go hand in hand with significant NHS discounts.

As part of the Voluntary Scheme agreement, the NHS made a number of commitments aimed at improving access to medicines. These include that from 2020, all new innovative medicines should receive NICE appraisals unless there are clear reasons not to assess them. There was also a commitment to increase commercial flexibility, giving the NHS scope to engage with industry and agree bespoke pricing and access deals with companies.

Statutory Scheme

Manufacturers or suppliers of branded medicines to the NHS who do not participate in the Voluntary Scheme are, by default, subject to the so-called "Statutory Scheme" (per sections 262–264 of the NHS Act 2006).

The Government revised the Statutory Scheme significantly in 2018 through the Branded Health Service Medicines (Costs) Regulations 2018 (the "2018 Regulations"). The 2018 Regulations came into force on 1 April 2018 and were subject to further amendments between 1 January 2019–1 April 2020. Currently, the Statutory Scheme includes the following features:

- Manufacturers or suppliers must pay a percentage of their net sales of branded products to the NHS on a quarterly basis. The percentage payable is 7.4% for 2020 and will be 10.9% for 2021 and subsequent calendar years. The percentages for 2020 onwards are approximately half of those the initial version of the scheme predicted.
- There are also pricing controls, such as:
  - The maximum price of a product that was on the market on 1 December 2013 is capped to the price at that date, subject to any agreed increases.
  - Price increases and the price of new presentations require the agreement of the Secretary of State, who must take into account factors including: (i) the clinical need for the product; (ii) the cost of therapeutically equivalent or comparable products (including in other European Economic Area countries); (iii) if the product contains a new active substance; and (iv) estimated profits and other financial parameters, etc.
- Unless the Voluntary Scheme applies, the Statutory Scheme will encompass all biologic medicines supplied to the NHS, including biosimilars.

The revisions to the Statutory Scheme bring it more closely in line with the Voluntary Scheme, though there are some differences. Arguably, pricing arrangements for products

containing new active substances are more straightforward under the Voluntary Scheme than the alternative. Importantly, the rebates that the industry must pay back to the Department of Health are broadly aligned and have fallen from initial projections.

Factors that affect pricing

A number of factors affect drug pricing in the UK, ranging from Government and NHS policies, commercial arrangements between companies and the NHS, and marketplace competition. Note, the UK list price is often a benchmark for countries that operate reference pricing systems. This can be an important consideration for companies, which encourages providing discounts to the NHS under agreements that do not affect the reference price.

As noted above, companies must price branded products in accordance with the Voluntary or Statutory Schemes. The schemes tightly control increases in the price of established branded medicines but provide more (though unlikely complete) flexibility when pricing new products. New, innovative products are very likely to be subject to a NICE appraisal and companies try to meet NICE's cost-effectiveness criteria, if at all possible. If that is not feasible, companies often consider methods to provide better value for money to the NHS, such as through Patient Access Schemes or Managed Access Agreements.

Even after companies have agreed a price under the Voluntary or Statutory schemes and a NICE appraisal has taken place, there are various forces within the NHS that can further reduce the price that a company actually charges for its products. The importance of those aspects has grown in recent years, which reflects the increasingly multi-layered landscape for drug pricing in the UK. Often, the discounts that a company is prepared to offer the NHS will affect its level of uptake and use.

For example, NHS Hospital Trusts, CCGs and other NHS bodies rely heavily on tenders, rebate agreements and other commercial arrangements to purchase generic and branded products with additional discounts. In particular, the NHS increasingly uses Framework Agreements (structured agreements in which a consortium of NHS "buyers" can purchase products for centrally contracted prices), which can significantly affect the price a supplier receives. "Framework Agreements" are regulated under the UK Public Contracts Regulations 2015.

The NHS in England increasingly takes a joined-up approach to procurement and medicines optimisation. For example, the NHS has established several national and regional procurement groups to co-ordinate and support medicines procurement, sharing information and expertise. Similar groups exist to align local formularies and prescribing policies to the most cost-effective options available, which can stimulate companies to offer keener prices to remain locally recommended or on a preferred formulary.

As in most other markets, competition from generic and biosimilar products also affects the price of innovator products on the market. The NHS' policy, for some time, has been to encourage clinicians to prescribe most products by their International Non-proprietary Name ("INN") to encourage generic prescribing and dispensing. Many NHS organisations (such as CCGs or Hospital Trusts) also run programmes to switch patients from innovative to generic or biosimilar products. These factors mean that once generic or biosimilar products enter the market, suppliers of innovative products can rapidly lose market share unless they reduce prices. Note, that in general UK prohibits generic or biosimilar substitution in pharmacies for a brand-name prescription. However, certain exceptions apply. For example, substitution may be permitted in hospitals in some cases. Also, pharmacy-level substitution is lawful if provided for under a "Serious Shortage Protocol" (which is a statutory mechanism that amends pharmacy dispensing rules if the Department of Health considers there is a serious shortage of one or many medicines in the UK).

The NHS generally avoids intervening in the market for generic products, relying on market forces to regulate it. However, over the last three years, the NHS has experienced severe shortages in the supply of certain generic medicines. Reportedly, this is the result of Brexit-related uncertainty and a variety of other supply-side issues. These shortages have led to price increases and the NHS has, in some cases, reflected this by offering a higher reimbursement amount in the Drug Tariff, often on a temporary or *ad hoc* basis.

Policy issues that affect pricing and reimbursement

The NHS' medicines policies aim to balance a number of interests, including:

- obtaining value for money for taxpayers;
- ensuring there is equitable access to treatment for NHS patients; and
- stimulating innovation in the life sciences industry by reimbursing new products that demonstrate clinical and cost-effectiveness.

However, demographic change, an increase in spending on prescription medicines, and budgetary pressure, make it increasingly difficult to maintain this balance.

The UK's population is growing as well as becoming older. The Office for National Statistics projects the UK's population to increase from approximately 66.4 million people in 2018 to approximately 69.4 million people by 2028. In that time, the proportion of the population over the age of 65 in England would increase from 18.2% to 20.7%. The rising number of older people has increased the demand for healthcare and the volume of products dispensed, particularly those to treat age-related conditions, such as cardiovascular disease and diabetes.

As noted above, the volume and cost of drugs used in and/or reimbursed by the NHS is on a steady upward trajectory. Population and demographic changes are major contributing factors. Another reason is an increase in high-cost innovative medicines NHS, particularly those used in hospital and specialist settings.

Historically, while the overall NHS budget continued to grow, this growth was outpaced by the rising cost of medicines (both in terms of volume and price). That context affected the UK's approach to controlling the price of medicines (particularly when the Voluntary and Statutory Schemes were re-cast in 2018/19). The Voluntary and Statutory Schemes have so far delivered savings to the public purse. The percentage amounts that the Government claws-back from the industry under both schemes has fallen in 2020 from early projections, which suggests the rising cost of branded medicines is now better controlled. Nevertheless, the NHS remains focused on delivering efficiencies and focusing on priority areas. The multi-layered landscape that affects drug pricing, uptake and procurement is likely to evolve and be further enhanced.

Emerging trends

The pricing and reimbursement landscape in the UK is constantly evolving, at various levels (including, for example, the approach the NHS takes to deliver best-value). We discuss some of the key trends below:

- The NHS is committed to speeding-up access to promising technologies in specific, priority treatment areas. The NHS's Accelerated Access Collaborative ("AAC") identifies game-changing innovations and provides their manufacturers with strategic support to ensure rapid uptake within the NHS. Recently, the AAC identified tumour-agnostic oncology and histopathology-independent drugs and advanced therapy medicinal products ("ATMPs") as a particular area of interest.

- Although a review process is underway, NICE's cost-effectiveness criteria and Budget Impact Test are currently relatively rigid and have remained so for several years. In effect, this means that companies (particularly of high-cost drugs) are increasingly having to negotiate agreements with the NHS (e.g., through Managed Access Agreements or Patient Access Schemes), by which a positive NICE recommendation becomes possible. Usually, that involves significant discounts from the product's list price.
- There is growing evidence of the NHS exercising its strengthened mandate to negotiate bespoke, confidential pricing and access deals with pharmaceutical companies either alongside or outside the parameters of a NICE appraisal. For example, in October 2019, the NHS concluded long-running discussions by agreeing a deal with Vertex Pharmaceuticals to enable NHS funding for three cystic fibrosis products licensed in the UK.
- Co-ordinated procurement has emerged as a key tool for the NHS to achieve best-value in purchasing medicines for hospital or specialist settings. Depending on the therapeutic area, the NHS co-ordinates tendering centrally, often resulting in Framework Agreements awarded at the regional (or even supra-regional) level. As a result, particularly in a competitive market, pharmaceutical companies find themselves under pressure to offer further discounts to the NHS at the tendering stage. The co-ordinated approach has led to medicines procurement litigation and this is likely to be a growing trend. For instance, in early 2019, there was an unsuccessful attempt to overturn an NHS procurement programme for products to treat and eliminate Hepatitis C, the largest drug tender the NHS has ever undertaken.
- The NHS' internal structure and policies often incentivise local organisations to purchase "best value" products, particularly generics and biosimilars. NHS organisations that fall short of this are potentially vulnerable to financial penalties or disincentives. For example, NHS-organised Regional Medicines Optimisation Committees also provide targeted guidance to CCGs and clinicians about savings associated with switching to biosimilars. The overall aim is to switch 90% of new patients and 80% of existing patients to the cheapest available biological product within three to 12 months of its UK launch. Similarly, in some therapeutic areas, the NHS publishes internal "reference prices" that limit the amount that an NHS hospital receives from central NHS funding if the hospital purchases products that exceed the relevant reference price.
- Linked to this is the growing tendency for the NHS to support using unlicensed products (or licensed products off-label) for reasons of cost. Historically, the NHS respected the principle of using licensed products within their label wherever possible, which is consistent with the MHRA's position and professional guidelines for doctors. Similarly, NICE's position is that it cannot positively recommend unlicensed products or off-label use of licensed medicines in an assessment (though it sometimes takes this into account for cost-comparison purposes). Despite this, the NHS has in certain high-profile cases advocated using lower-cost, unlicensed or off-label products. This is highly controversial, having been the subject of High Court and recent Court of Appeal litigation in respect of reformulated bevacixumab for intra-ocular use.
- NHS organisations continue to seek increasing amounts of information from internal and external sources about product pricing (e.g., discounts). The Health Service Medical Supplies (Costs) Act 2017 gives the Secretary of State wide-ranging powers to demand a variety of information from all stages in the medicines supply chain. Anecdotally, the NHS expects more transparency from companies to help it achieve better value for money, particularly in areas where there has traditionally been price opacity (e.g., generics). Similarly, there is a growing expectation that NHS bodies that enter into

commercial agreements with suppliers will share this information within the NHS with a view to deriving the best value nationally.

- The industry continues to face scrutiny from the UK Competition and Markets Authority ("CMA"). In particular, the CMA has investigated alleged anti-competitive agreements and conduct and suspected excessive and unfair pricing. Largely, this concerns allegations that manufacturers of generic products have inappropriately increased prices of products for which there is no meaningful competition.
- Although the UK has formally exited the EU, there continues to be uncertainty as to EU/UK relations following the end of the so-called "Withdrawal Period" on 31 December 2020. These uncertainties have had an indirect effect on availability of medicines. The UK has implemented measures to outlaw exporting or stock-piling certain medicines (largely generics and products where there is significant parallel trade), designed to alleviate shortages and price-volatility. In the longer term, and subject to ongoing EU/UK negotiations, this could have knock-on effects in the mainstream branded products market (particularly combined with Serious Shortage Protocol rules).

  The long-term impact of COVID-19 on the NHS and the medicines landscape is unknown. The Government is committed to providing significant additional resources to the NHS and supporting life-sciences companies. However, this is principally to manage the current health crisis and may not be sustainable in the longer term, particularly as the UK enters into a deep forecasted recession. One could not rule out drastic changes in the medicines pricing and reimbursement environment in future.

Successful market entry

Formulating a successful strategy for market entry will depend on the type of product in question and its place in the NHS' complex architecture. The following are some general points to consider:

- **NICE appraisal**. A company should investigate whether its product will be subject to a NICE appraisal and if so, whether it could meet NICE's cost-effectiveness criteria. The company could also explore qualifying for HST status or the Cancer Drugs Fund. For high-cost products, the company should consider the possibility of offering a Patient Access Scheme.
- **Specialised commissioning categories**. Falling within the scope of Specialised Services, Highly Specialised Services, the Cancer Drugs Fund or benefitting from Accelerated Access Collaborative Support would increase the likelihood of a high-cost product receiving NHS funding.
- **Appreciating the NHS' approach to commissioning and procurement**. It is critically important to appreciate the NHS' multi-layered approach to medicines pricing and purchasing. In particular, that achieving a list price and a NICE recommendation are not always determinative of the price that the NHS will pay for a product. The NHS can seek to achieve value through a variety of mechanisms, including tendering and direct negotiations with the industry. Companies should therefore consider their pricing and discount strategy in a holistic way. This is particularly important if a product's main use is in secondary care.
- **Understanding NHS prescribing policies**. In the UK, market penetration is often a greater concern for companies than market entry. The NHS' prescribing policies (both local and national) have a significant impact on the uptake of a new product. Understanding these is therefore important.

Endnotes

1. Regulation 5 of the Human Medicines Regulations 2012.
2. See also Regulation 220 of the Human Medicines Regulations 2012.
3. "Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs" NHS, 29 March 2018.
4. Schedule 1 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
5. Schedule 2 to the NHS (General Medical Services Contracts) (Prescription of Drugs, etc.) Regulations 2004.
6. Pursuant to the Health and Social Care Act 2012.
7. Regulations 7(2)-(3) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (SI 2013/259) and as set out in the NHS Constitution.

Grant Castle
Tel: +44 20 7067 2006 / Email: gcastle@cov.com

Grant Castle is a partner in the London office of Covington & Burling LLP, practising in the areas of life sciences regulatory law, with an emphasis on pharmaceutical and medical device regulation and associated compliance issues. He has assisted clients with a variety of UK pricing and reimbursement issues, including representing suppliers of pharmaceutical products and medical devices and other interested parties in a number of successful NICE appeals and administrative proceedings in the UK and EU courts.

He speaks and lectures frequently on regulatory issues in both the pharmaceutical and medical device areas at the University of Surrey, the University of Wales and Cranfield University. He received a BSc in chemistry with first-class honours from Imperial College of Science, Technology and Medicine in London in 1991 and a Ph.D. in organic chemistry from Trinity College, University of Cambridge in 1994.

Brian Kelly
Tel: +44 20 7067 2392 / Email: bkelly@cov.com

Brian Kelly is a partner in the London Life Sciences group, whose practice focuses on EU food and drug regulatory law, public and administrative proceedings, public procurement matters, European Union law and product liability and safety.

Mr. Kelly has advised and successfully represented a variety of clients in respect of NICE appeals. He has advised clients on establishing joint working and risk-sharing relationships with the NHS in England and Wales. Mr. Kelly has also successfully represented life-sciences clients in judicial reviews and other administrative proceedings in the UK in respect of NHS procurements. Mr. Kelly holds a degree in neuroscience and is an honorary lecturer at University College London.

Raj Gathani
Tel: +44 20 7067 2266 / Email: rgathani@cov.com

Raj Gathani is an associate in Covington & Burling LLP's London office. Raj's practice includes advising clients on variety of UK pricing and reimbursement matters, including Drug Tariff listing and the Voluntary and Statutory Pricing Schemes. He has first-hand experience of drug reimbursement matters, having spent eight years operating a pharmacy business prior to joining Covington & Burling LLP.

Covington & Burling LLP

265 Strand, London WC2R 1BH, United Kingdom
Tel: +44 20 7067 2000 / URL: www.cov.com

www.globallegalinsights.com

Other titles in the **Global Legal Insights** series include:

- **AI, Machine Learning & Big Data**
- **Banking Regulation**
- **Blockchain & Cryptocurrency Regulation**
- **Bribery & Corruption**
- **Cartels**
- **Corporate Tax**
- **Employment & Labour Law**
- **Energy**
- **Fintech**
- **Fund Finance**
- **Initial Public Offerings**
- **International Arbitration**
- **Litigation & Dispute Resolution**
- **Merger Control**
- **Mergers & Acquisitions**
- **Pricing & Reimbursement**

Strategic partner